

Translation

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PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference HKM0211	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/JP02/09377	International filing date (day/month/year) 12 September 2002 (12.09.02)	Priority date (day/month/year) 20 March 2002 (20.03.02)
International Patent Classification (IPC) or national classification and IPC A61K 9/14, 47/38, 47/02, 47/34		
Applicant HOSOKAWA MICRON CORPORATION		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of <u>4</u> sheets, including this cover sheet.  <input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).  These annexes consist of a total of _____ sheets.
3. This report contains indications relating to the following items:  I <input checked="" type="checkbox"/> Basis of the report II <input type="checkbox"/> Priority III <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability IV <input type="checkbox"/> Lack of unity of invention V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement VI <input type="checkbox"/> Certain documents cited VII <input type="checkbox"/> Certain defects in the international application VIII <input type="checkbox"/> Certain observations on the international application

Date of submission of the demand 14 July 2003 (14.07.03)	Date of completion of this report 29 October 2003 (29.10.2003)
Name and mailing address of the IPEA/JP	Authorized officer
Facsimile No.	Telephone No.

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/JP02/09377

## I. Basis of the report

### 1. With regard to the elements of the international application:\*

- ☒ the international application as originally filed
- ☐ the description:  
 pages \_\_\_\_\_, as originally filed  
 pages \_\_\_\_\_, filed with the demand  
 pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☐ the claims:  
 pages \_\_\_\_\_, as originally filed  
 pages \_\_\_\_\_, as amended (together with any statement under Article 19  
 pages \_\_\_\_\_, filed with the demand  
 pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☐ the drawings:  
 pages \_\_\_\_\_, as originally filed  
 pages \_\_\_\_\_, filed with the demand  
 pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☐ the sequence listing part of the description:  
 pages \_\_\_\_\_, as originally filed  
 pages \_\_\_\_\_, filed with the demand  
 pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_

### 2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

### 3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

### 4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets/fig \_\_\_\_\_

### 5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\*

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

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## V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

### 1. Statement

Novelty (N)	Claims	9-31	YES
	Claims	1-8	NO
Inventive step (IS)	Claims		YES
	Claims	1-31	NO
Industrial applicability (IA)	Claims	1-31	YES
	Claims		NO

### 2. Citations and explanations

- Document 1: US 5336271 A (Nara Machinery Co., Ltd.), 9 August 1994
- Document 2: JP 10-218763 A (Kaneka Corp.), 18 August 1998
- Document 3: WO 00/24379 A1 (Tanabe Seiyaku Co., Ltd.), 4 May 2000
- Document 4: EP 600528 A1 (Sterling Winthrop Inc.), 8 June 1994
- Document 5: JP 11-504930 A (Schering AG), 11 May 1999
- Document 6: WO 95/22963 A1 (Medinova Medical Consulting GmbH), 31 August 1995

#### Claims 1-8

The inventions set forth in claims 1-8 are not novel and do not involve an inventive step in the light of document 1, cited in the international search report.

Document 1 discloses a dry method for forming particle composites, which does not require an organic solvent or water, by employing impact in a high-speed stream of gas, as a process for producing solid medicinal preparations. It also mentions that a substance such as a cellulose or a starch can be used for the core particles in said solid preparations, that a size in the range of 0.5  $\mu\text{m}$  to 1 mm is suitable for the core particles, and the

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use of an anti-inflammatory or antipyretic analgesic drug such as ibuprofen as the drug (claims; column 1, lines 39-56; column 3, lines 42-56; and column 4; lines 1-18).

In addition, a person skilled in the art could easily set the average particle size of the particles and the content of the drug within optimum ranges by means of experimentation.

**Claims 9-31**

The inventions set forth in claims 9-31 do not involve an inventive step in the light of documents 2-6, cited in the international search report.

Document 2 discloses preparations for transpulmonary absorption which are produced by granulation of particles containing a principal drug (particle size:  $\mu\text{m}$  dimensions) using a composite fluidized bed device such as an Agglomaster (Hosokawa Micron Corp.). Document 3 also discloses spherical particles (particle size:  $\mu\text{m}$  dimensions) including an active ingredient such as an antipyretic, analgesic and/or anti-inflammatory agent and produced in a granulating device such as an Agglomaster (Hosokawa Micron Corporation). And, as disclosed in documents 4-6, use of nanoparticles in solid preparations is known. Therefore, a person skilled in the art could easily investigate the use of particles of nanometer dimensions as the particles employed to produce solid preparations in the inventions disclosed in documents 2 and 3.

Moreover, a person skilled in the art would not require special inventive skill to use experimentation to investigate the establishment of an optimum range for the average particle size of the particles, or investigate optional addition of universally used constituents such as lubricants.